

REMARKS

Claims 1 to 23, 28, 29 and 32 are pending and stand finally rejected under 35 U.S.C. § 103 as allegedly obvious over Young, LE, “Cardiac responses to training in 2-year-old Thoroughbreds: an echocardiographic study” (Young 1), in view of Young, LE, “Relative wall thickness: a useful indicator of sports-specific cardiac adaptations to training in horses” (Young 2). Applicants respectfully traverse this rejection. No claim amendments are made herein.

As an initial matter, Applicants respectfully submit that the designation of the Office Action as final is improper. Applicants successfully overcame all rejections raised in the previous Office Action, because the reference designated as Young 2 in that first Office Action was not prior art. The reference cited as Young 2 in the second Office Action dated January 4, 2008 is newly cited. Yet the second Young 2 reference was already of record before the first Office Action issued, and the subject matter added to claim 1 in the Applicants’ prior response was already present in a dependent claim that was only rejected by the combination of Young 1 with the first Young 2 reference that was not prior art. Thus, the new ground of rejection raised in the Office Action dated January 4, 2008 was neither necessitated by Applicants’ amendment of the claims nor based on information filed during the period set forth in 37 C.F.R. § 1.97(c). Accordingly, finality is not proper (*see* M.P.E.P. §107.07(a)), and Applicants respectfully request that full consideration be given to the instant response.

The invention recited in Applicants’ claims is directed to screening methods for selecting among racehorse candidates, and is based on their discovery that certain echocardiographic parameters, when compared to those of horses of about the same age, sex, and weight, can be useful predictors of a candidate’s future success as a racehorse. Claim 1, for example, relates to the use of ventricular septal wall width as such an indicator. Claim 5 relates to a method in which both the width of the candidate’s ventricular septal wall and the cross-sectional area of the left ventricle in diastole are measured, and claim 6 specifies that the candidate is selected if both of these indicators are greater than the corresponding mean values from a collection of measurements of horses of about the same age, sex, and weight. Additional parameters are recited in other dependent claims. Notably, the methods recited in

the instant claims do not require that the candidate's level of conditioning or training status be taken into account, as Applicants have found that the measurements have predictive value without taking training status into consideration.

Young 1 is directed to a study designed to evaluate the effects of commercial racehorse training on cardiac dimensions and indices of cardiac function in 2 year old Thoroughbred racehorses (*see*, page 195, col. 2). The author reports that ventricular wall thickness, chamber diameter and relative wall thickness ("RWT"-- an index of ventricular hypertrophy calculated by dividing the sum of left ventricular free wall and interventricular septal wall by the diameter of the left ventricle) all increased as an adaptive response to "a commercial training programme." *See* p. 197, col. 1. No age-matched control group was analyzed, and the author suggests that the constraints of commercial training preclude the obtaining of such data (*see id.*). Nonetheless, the author concluded that commercial flat race training in horses produces adaptive responses of considerable magnitude (*see id.*, at page 198, col. 1), suggesting that measurements taken on their own, without correlation to training history, would be of little or no predictive value.

Young 2 relates to analyses of RWT in different type of equine athletes. The brief article reports that RWT values for endurance horses are less than those for racehorses, and also that among racehorses, sprinters tend to have higher RWT values than distance horses. Based on this data, the author concludes that RWT might be used to predict optimal race distances for Thoroughbreds. *See* Young 2, page 555, col. 1. Notably, Young 2 reports that "there was no significant change in RWT with training in the group of flat-racing Thoroughbreds." Thus, at least in this regard, the article appears to directly contradict the findings of Young 1.

The Office Action combines these two articles and alleges that the instant claims are obvious. Applicants respectfully submit that the Action improperly combines the two references, misinterprets the references, and arrives at the conclusion of obviousness only through impermissible hindsight reasoning.

Applicants submit that Young 1 and Young 2 may not properly be combined as is done in the Office Action, because the two references directly conflict with each other in their teaching. The Action acknowledges that Young 1 describes measuring the septal wall, but does not disclose the relevance of this measurement to selecting racehorse candidates. However, the Action states that Young 2 “does disclose selecting a racehorse candidate by comprising septal wall measurements of horses.” *See* Office Action at page 3. In fact, as discussed above, Young 1 states that septal wall thickness and RWT both increase in response to training, indicating that the level of training must be considered when comparing horses at different levels of fitness, while Young 2 states that RWT *is not* significantly changed in response to training (*see* page 555, col. 2). Which of these statements is one of ordinary skill in the art to believe? Applicants respectfully submit that those skilled in the art would not be able to combine these two disparate teachings and conclude that ventricular wall thickness is a suitable indicator of future success as a racehorse, because the two references disagree over the relevance of training to this variable.

Further, while Young 2 would indicate that there are differences in RWT measurements for horses that perform in different types of races, there is no indication that such measurements may be obtained from young horses, such as those being auctioned at yearling and two year old sales, where horses have not yet undergone any serious training, and used to predict which are more likely to go on to have successful careers. To enable the *predictive* importance of any such variable, one would need to amass large volumes of data from a number of young horses, follow the horses through their careers, and determine which measurements taken *prior* to starting their careers are statistically correlated with success *during* their racing careers. The Applicants have done just that, conducting measurements on over 7000 Thoroughbred yearling and two-year old racing candidates (*see* Specification, ¶ 0043), following their careers, and determining which of the many variables that may be assessed *prior* to the start of their racing careers are statistically correlated with future racing success. At most, Young 2 teaches that endurance horses, as a group, have lower RWT indices than racehorses, and that among racehorses, sprinters have higher RWT indices than routers. It is only with the teachings of the instant application that one can fully understand that particular cardiac measurements such as septal wall thickness and cross-sectional

ventricular area during diastole may be used to discriminate between young racehorse candidates and used to select candidates that will have an increased likelihood of going on to a successful racing career.

In addition, neither Young 1 nor Young 2 teach or suggest the importance of considering age, weight and sex in determining whether a candidate's septal wall thickness may be a useful indicator of future success. Indeed, Young 1 specifically suggests that commercial training constraints preclude use of age-matched controls (Young 1, page 197, col. 1), while Young 2 is silent on the matter. Thus, to the extent that either reference could be considered to suggest that septal wall thickness may have predictive value, neither would teach or suggest that measurements obtained from a particular candidate should be compared to measurements from a group of horses of about the same age (*i.e.*, having a date of birth within about 30 days), sex, and weight (*i.e.*, having a weight within about 25 pounds)¹ as said racehorse candidate, as recited in the instant claims, and Young 1 wrongly suggests that this may not be possible in the commercial environment.

Moreover, to the extent that one would rely on either article as a teaching that RWT may be used to predict a candidate's suitability as a racehorse, in Applicants' methods, candidates may be selected if BOTH septal wall thickness and left ventricular cross-sectional area (which increases proportionally with left ventricular diameter) are greater than the mean values of each in horses of about the same age, sex, and weight (*see, e.g.*, claims 5 and 6). Young 1 and Young 2, on the other hand, teach that these values go in the *opposite direction* of each other: since RWT is a function of wall thickness *divided by* ventricular diameter, if one were to read Young 2 as a suggestion to select horses having an increased RWT for racing (as opposed to endurance events), one would be led to select horses having a *lower* ventricular diameter, which is contrary to the teachings of the instant application. Thus, at least claims 6 and 7 must be considered allowable over the cited references for this reason, as well.

Applicants submit that because the Office Action does not make out a *prima facie* case of obviousness, the rejection of claim 1 should be withdrawn. MPEP § 2143; *In re*

¹ See Specification, paragraph [0037].

Vaeck, 947 F.2d at 492. Because the rejection of independent claim 1 is improper and should be withdrawn, the obviousness rejections of all dependent claims related to claim 1 should also be withdrawn and those dependent claims should be allowed. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (a claim depending from a non-obvious independent claim is itself nonobvious). Moreover, several of these claims contain elements that are neither disclosed nor suggested by any proper combination of Young 1 and Young 2. The difference between RWT and the subject matter of claims 5 to 7 has been discussed previously. It is further noted that these claims, as well as claim 10, relate to the use of the cross sectional area of the left ventricle in diastole. As taught in Young 1 and Young 2, RWT is determined based on the *diameter* of the ventricle, not the *cross-sectional area*. Since cross-sectional area increases by the radius *squared*, the two measurements are not the same. Moreover, neither reference attaches any significance to measurements of ventricular cross sectional area during *systole*, as recited in claims 12 to 14.

Similarly, dependent claim 8 describes a specific method of measuring the ventricular septal wall width that is not disclosed in either of the cited publications (*see* Figure 3 of the instant application). Claims 15 to 17 recite the use of measurements of splenic cross sectional area, and claims 18 and 19 recite the use of measurements of the candidate's height times weight. Young 1 and Young 2 are completely silent about the relevance of the size of the spleen and height times weight to the cardiac parameters discussed therein, and neither of the references contain any suggestion that these parameters, in combination with the cardiac measurement recited in claim 1, may be of any predictive value among racehorse candidates. The Office Action indicates that the relevance of these parameters would be known to those skilled in the art, but provides no basis for arriving at this conclusion. Thus, Applicants respectfully submit that a *prima facie* showing has not been made for any of these claims, as well.

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**PATENT
REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116**

CONCLUSION

In view of the foregoing, Applicants respectfully submit that Young 1 and Young 2 fail to render any of the instant claims obvious, and request that the rejection be withdrawn. A Notice of Allowance of all of pending claims 1 to 23, 28, 29 and 32 is earnestly solicited.

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